Remarks

Claims 25-47 are currently pending. Claim 48 has been withdrawn from examination, however, Applicants acknowledge the Examiner's intent to rejoin Claim 48 once claims 25-47 are allowed. See, Paper No. 10312005, pages 3-4.

I. Rejections of claims 25-47 under 35 U.S.C. § 101

Claims 25-47 have been rejected under 35 U.S.C. § 101 for allegedly not being supported by either a specific, substantial, or credible asserted utility or a well-established utility. Specifically, the Examiner asserts: "The utility of the claimed antibody resides in the polypeptide it binds. The specification, however, fails to provide objective evidence of any function for the protein." (Paper No. 10312005, Page 5). Moreover, the Examiner further states "the specification does not disclose any activities, diseases or conditions known to be associated with the protein," and that "the utilities identified by the applicant are not specific or substantial." (Page 6, Paper No. 10312005).

Applicants respectfully disagree and traverse. Under section 2107.01 of the M.P.E.P. (8th edition, revision 3), a specific, substantial and credible utility is defined as: (1) a utility specific to the subject matter claimed, (2) a utility that defines a real world use, such as a therapeutic method of treating a known or newly discovered disease, (3) where credibility of the utility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record. In addition, the M.P.E.P. further states that "an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112, additional statements of utility, even if not 'credible' do not render the claimed invention lacking in utility." (M.P.E.P. § 2107.02 at I. See also, M.P.E.P. § 2107 at II.B.(1)(ii)).

Applicants respectfully submit that the present specification discloses a specific, substantial, and credible utility for the claimed invention. For example, the specification states that "polynucleotides and polypeptides corresponding to [gene 16 or HQAHD50], as well as antibodies against those polypeptides, may be useful for the diagnosis, prevention, and/or treatment of cancer and other hyperproliferative disorders. (Page 38, lines 6-10). Thus, the present specification discloses a utility for the claimed antibodies and polypeptides of the invention that is specific and substantial, since not all polypeptides or antibodies

against polypeptides can be used to diagnose, prevent, and/or treat cancer and other hyperproliferative disorders.

Applicants further respectfully submit that this asserted utility is credible, given the state of the art and the disclosure of the present application. For example, the present specification discloses that the polypeptide of the claimed invention is specifically expressed in a number of cancers including prostate adenocarcinoma, pancreatic carcinoma, breast cancer, rectal tumors, ovary tumors, colon tumors, kidney tumors, chronic lymphotic leukemia, and Ewing's sarcoma. To one of ordinary skill in the art, the specific expression of the polypeptide of the invention in a broad range of tumor-types and cancers would support the asserted utility (particularly for antibodies) in diagnosing, preventing, and/or treating cancer and other hyperproliferative disorders.

In support of this assertion, Applicants respectfully direct the Examiner's attention to Vasmatzis et al. "Discovery of Three Genes Specifically Expressed in Human Prostate by Expressed Sequence Tag Database Analysis." *Proc. Natl. Acad. Sci. USA*, 95:300-304 (1998), (**Exhibit A**), where it is stated: "genes that are specifically expressed in one particular tissue or organ...could be useful in the diagnosis or therapy of cancer," and Olsson et al. "PRAC2: A New Gene Expressed in Human Prostate and Prostate Cancer." Prostate, 56(2):123-30 (2003), originally submitted as reference AH in Applicants last communication of October 17, 2005 (**Exhibit B**), where it is stated: "the detection and treatment of cancer would potentially benefit from the identification of new genes that are specifically expressed in prostate cancer." (Page 123, left column, lines 7-10). Indeed, as stated above, the polypeptide of the invention is not only specifically expressed in prostate cancer, but also in a number of other cancers. Thus, both the state of the art and the disclosure of the present application support that the present specification discloses a specific, substantial, and credible utility, which would be readily apparent to one of skill in the art.

Moreover, the Examiner contends "neither the specification, nor the sequence search ... has indicated significant homology to any known functional protein domains." Applicants respectfully disagree and traverse.

As a preliminary matter, Applicants request the Examiner to forward the sequence search results alluded to on page 7 of the present Office Action (Paper No. 10312005), as it appears these results were inadvertently not forwarded to Applicants.

Nonetheless, in contrast to the Examiner's assertion, Applicants respectfully direct the Examiner's attention to **Exhibit C**, a sequence alignment between SEQ ID NO:213 (HQAHD50, Table 1C) and PRAC2, a gene expressed in prostate cancer (See, **Exhibit B**), which shows that the polypeptide of the instant invention is nearly identical to PRAC2 (98.9% identity).

Therefore, a nexus exists between the well known role of specific gene expression and its use in cancer diagnosis, prevention, or therapy in the prior art; the present specification's disclosure that HQAHD50 is specifically expressed in a number of cancers including prostate cancer; and the post-filing date art which corroborates the potential role of HQAHD50 in the diagnosis, prevention, or therapy of prostate cancer.

Accordingly, Applicants respectfully submit that the rejection of claims 25-47, under 35 U.S.C. § 101 has been obviated. Thus, Applicants respectfully request that the rejection of claims 25-47 be reconsidered and withdrawn.

II. Rejections of claims 25-36 and 39-45 under 35 U.S.C. § 112

The Examiner rejected claims 25-36 and 39-45 under 35 U.S.C. § 112, first paragraph because the claimed invention is allegedly "not supported by either a specific, substantial and credible asserted utility or a well established utility." (Page 8, Paper No. 10312005). Applicants respectfully disagree and traverse.

Applicants respectfully submit that the Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. As discussed above, the claimed invention complies with the utility requirement of 35 U.S.C. § 101. Accordingly, Applicants respectfully request that the rejection of claims 25-36 and 39-45 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: March 17, 2005

Respectfully submitted,

By _____

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